CLAIMS

What is claimed is:

Claim 1. A diagnostic marker including a binding protein indicative of a loss of self tolerance of Schwann cell protein comprising:

an autoantibody or an immunologically detectable fragment thereof capable of recognizing an epitope of Schwann cell breakdown.

Claim 2. The diagnostic marker of claim 1 wherein:

said autoantibody is capable of recognizing an epitope of glial fibrillary acidic protein.

Claim 3. A diagnostic assay test kit for diagnosing the existence, pre-disposition or risk of developing an autoimmune disease in a patient said kit comprising:

a front panel comprising a sample window and a display window, the sample window to receive a bodily fluid from said patient;

a back panel; and a dry chemistry membrane affixed between the front and back panels positioned for display in at least the display window,

wherein, said membrane comprises:

a sample region and a control region, said sample region positioned to receive the sample from the sample window; and

at least one antibody pair located at a discrete location along said membrane between the sample region and the control region, each of said antibody pairs comprising an antibody reagent member and an immobilized capture antibody member, each capture antibody member being located on said membrane closer to the control region than the corresponding antibody reagent member, each antibody pair having a measurable or observable moiety labeled or chemically bonded to the antibody reagent member of each said antibody pairs, the antibody pairs being monoclonal or polyclonal and comprising:

at least one antibody pair that specifically binds to a marker of Schwann cell injury or cell death,

such that upon adding sample to the sample window, analytes present in the sample and complementary to the antibody pairs will migrate toward the control region, binding to the antibody pair each of said analytes, producing a color change proportional to the each of analyte present from which a diagnosis of autoimmune disease is made.

Claim 4. The diagnostic assay test kit of claim 3 wherein:

said autoimmune disease is selected from the group consisting of diabetes, prediabetes and multiple sclerosis and pre-multiple sclerosis.

Claim 5. The diagnostic assay test kit of claim 3 wherein:

said marker of Schwann cell injury or cell death is selected from the group consisting of glial fibrillary acidic protein (GFAP), S100 and GAD65.

Claim 6. The diagnostic assay test kit of claim 3 wherein:

said body fluid is selected from the group consisting of blood, blood components, urine, saliva, lymph and cerebrospinal fluid.

Claim 7. A process for detection of Schwann cell autoantibody as a marker for the presence, predisposition or risk for development of an autoimmune disease comprising the steps of:

drawing a sample of body fluid from a patient,

depositing the sample in a sample window of a diagnostic test kit, said test kit comprising

a front panel comprising a sample window and a display window;

a back panel; and

a dry chemistry membrane affixed between the front and back panels positioned for display in at least the display window, wherein said membrane comprises:

a sample region, and a control region, said sample region positioned to receive the sample from the sample window; and

at least one antibody pair located at discrete locations along said membrane between the sample region and the control region, each said antibody pair comprising an antibody reagent member and an immobilized capture antibody member, each capture antibody member being located on said membrane closer to the control region than the corresponding antibody reagent member, each antibody pair having a measurable or observable moiety labeled or chemically bonded to the antibody reagent member of each said antibody pair,

each said at least one antibody pair being monoclonal or polyclonal and comprising:

at least one pair that specifically binds to a marker of Schwann cell injury or cell death,

such that upon adding sample to the sample window, analytes present in the sample and complementary to the antibody pairs will migrate toward the control region, binding to the antibody pair each of said analytes, producing

a color change proportional to each concentration of analyte present, and

visualizing or measuring the moiety and diagnosing the presence of an autoimmune disease.

Claim 8. The process of claim 7 wherein said autoimmune disease is selected from the group consisting of Type 1 diabetes, prediabetes, pre-multiple sclerosis and multiple sclerosis.

Claim 9. The process of claim 7 wherein:

said Schwann cell autoantibody is autoreactive with Glial Fibrillary Acidic Protein (GFAP).

Claim 10. The process of claim 7 wherein:

said Schwann cell autoantibody is autoreactive with GAD-65.

Claim 11. A diagnostic assay kit for autoimmune disease comprising:

at least one immunologically reactive marker having an affinity for glial fibrillary acidic protein (GFAP), and

a means for determining binding between each of said respective markers and each of said respective antibodies.

Claim 12. Anti-GFAP IgG useful as a predictive marker of autoimmune disease.

Claim 13. A process for prediabetes screening and staging comprising:

drawing a sample of body fluid from a patient,

contacting said sample with a diagnostically effective amount of an anti-GFAP IgG useful as a predictive marker of Type 1 diabetes, and

determining binding between said anti-GFAP IgG and immunologically detectable fragments contained within said sample.

Claim 14. A process for interfering with the course, progression and/or manifestation of an autoimmune disease in a mammal comprising:

interfering with the disease process by administering to said mammal a therapeutically effective modality, said modality having a degree of immunological reactivity sufficient to modify the pathogenicity of lymphocytes specific in instigating loss of self tolerance of Schwann cell protein,

whereby said administration is effective to alter the course, progression and/or manifestation of said disease.

Claim 15. The process of claim 14 wherein said autoimmune disease is selected from the group consisting of

diabetes, prediabetes, multiple sclerosis and pre-multiple sclerosis.

Claim 16. A process for identifying a therapeutic moiety useful in treating diabetes, prediabetes, multiple sclerosis and pre-multiple sclerosis comprising:

recognizing at least one moiety for which a direct therapeutic value is predicted,

contacting said moiety with at least one biopolymer marker indicative or predictive of a disease state selected from the group consisting of diabetes, prediabetes, multiple sclerosis and pre-multiple sclerosis, and

determining modulation of said at least one biopolymer marker attributable to said therapeutic moiety;

whereby a product having a confirmed therapeutic value is identified.

Claim 17. The product identified via the process of claim 16.

Claim 18. A process for identifying a therapeutic moiety useful in treating diabetes, prediabetes, multiple sclerosis and pre-multiple sclerosis comprising:

recognizing at least one moiety for which an indirect therapeutic value is predicted,

contacting said moiety with at least one biopolymer marker indicative or predictive of a disease state selected from the group consisting of diabetes, prediabetes, multiple sclerosis and pre-multiple sclerosis, and

determining modulation of said at least one biopolymer marker attributable to said therapeutic moiety;

whereby a product having a confirmed therapeutic value is identified.

Claim 19. The product identified via the process of claim 18.

Claim 20. The process for interfering with the course, progression and/or manifestation of an autoimmune disease in a mammal in accordance with claim 14 wherein:

said therapeutically effective modality is an immunotherapeutic moiety defined as an effective analogue for a major epitope peptide in GFAP which pathogenicity of key lymphocytes which are specific for a native epitope in GFAP, said analogue having structural similarity but not identity in peptide sequencing able to be recognized by T-cells spontaneously arising and targeting an endogeneous self epitope,

whereby an altered T-cell activation occurs which leads to T-cell anergy or death.